IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A" TO THE INITIAL MOTION	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DENISE ELSER, MD

PRELIMINARY STATEMENT

Defendants' opposition to the *Daubert* motion to preclude Dr. Elser from offering opinions regarding adequacy of warnings acknowledges that this court has previously found that she is not qualified to offer these opinions based solely on her qualifications as a urogynecologist and has excluded those opinions. Defendants now seek to have the court revisit that decision on the basis that she relies not only on her own experience, but also on her historical review of the medical literature. (Defense Brief at 7). Defendants also argue that Dr. Elser should be permitted to offer the opinion that the risks of the TVT and TVT-O are well known to pelvic floor surgeons. However, Dr. Elser's warning opinions still suffer from the fatal flaw that she did not consider or consult **any** standard whatsoever, leaving her opinion devoid of any verifiable methodology, and her opinions on what risks are known to pelvic floor surgeons are speculation, and not based on any reliable methodology.

Defendants appear to concede that Dr. Elser is not qualified to offer any design opinions, except to say that the literature shows mesh is biocompatible. This, too, should be excluded as

Dr. Elser lacks the required expertise to opine biocompatibility issues. Her opinion regarding her personal revision rate with slings is not based on any scientifically reliable methodology, and Plaintiffs are unable to challenge the basis or veracity of this opinion. These opinions do not meet the *Daubert* standard and should be precluded.

LEGAL ARGUMENT

A. Dr. Elser failed to apply any objective standard in offering her warning opinions, in violation of *Daubert.*

This motion should be granted because Dr. Elser's opinions on the adequacy of the Ethicon's warnings are based only on Dr. Elser's subjective opinion, with no basis in or even verification with a standard from any source. The opposition brief is notable for its failure to identify any objective standard or methodology applied by Dr. Elser, and by which Dr. Elser's opinions on the warnings can be tested or objectively evaluated. That gap is fatal to warning opinions, as this Court recently has held. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *33. The same reasoning applies to Dr. Elser, who does not even know the purpose of the IFU. (Dr. Elser 9/16/14 Dep. Tr. 120:14-17, attached as Exhibit A). Dr. Elser knows no standards, and applied no reliable standard beyond her own subjective opinion:

> Q. All I'm saying is the opinions you're offering about the warnings are not based on any standard whatsoever as to what Ethicon was required to do because you don't know what they were required to do, right?
>
> A. No, I'm commenting on what the average pelvic surgeon needs to know.
>
> Q. Is the answer to my question yes?
>
> A. Yes.

(Dr. Elser 9/16/14 Dep. Tr., 168:17-169:4, Exhibit A). Such an opinion, not tied to any standard, is not permitted under *Daubert*. *Sanchez*, 2014 WL 4851989, at *33.

Dr. Elser also cherry-picks information and standards for her warning opinions, ignoring testimony from Ethicon's own physicians and pelvic floor surgeons. She disregards the testimony of key Medical Affairs personnel for Ethicon when their opinions do not match her own.

> Q. Doctor, have you reviewed or relied upon any depositions of any Ethicon company witnesses in forming your opinions in this case?
>
> A. I have read them, but I did not cite them in my report
>
> Q. Which ones have you read? Where would I get a list of all the company depositions that you've – that you've read.
>
> A. That I would have to look and see which ones I have in my file, but I was not planning to specifically cite them or rely on them. I did not rely on them for this report.
>
> Q. So, even though you've reviewed some depositions of Ethicon company witnesses, there is none that you intend to rely upon in forming your opinions in this case, is that correct?
>
> A. Yes.

(Dr. Elser 3/30/16 Dep. Tr. 14:23-15:26, attached as Exhibit B). This unreliable cherry-picking of data fails to satisfy the scientific standard under *Daubert*. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Products Liab. Litig.*, No. MDL214MN02502RMG, 2016 WL 1251828, at **13-14 (D.S.C. Mar. 30, 2016). Failing to adequately account for contrary evidence is not reliable or scientifically sound. *McEwen v. Baltimore Washington Med. Ctr. Inc.*, 404 Fed Appx. 789, 791-92 (4th Cir. 2010). For example, Charlotte Owens testified that the IFU needed to "clearly and unambiguously communicate" necessary warnings, and that they **"needed to list each of the adverse reactions that were known to you in Medical Affairs."** (Charlotte

Owens Dep. Tr. at 262:7-13, 309:23-310:3, attached as Exhibit C) (emphasis added). Similarly, David Robinson of Medical Affairs testified that the IFU **"should accurately represent what we knew to be risks,"** and that a complication would need to be listed if it had **"a frequency or a severity that had some implication for a risk/benefit ratio."** (David Robinson Dep. Tr. at 488:11-18, 489:4-10, 492:23-493:8, attached as Exhibit D) (emphasis added). Finally, Dr. James Hart, Chief Medical Officer of the Johnson & Johnson Global Surgery Group, testified that the purpose of the IFU is to:

> **provide a COMPLETE STATEMENT of what the company knows with regard to the indications, the contraindications, the warnings, the precautions and the adverse reactions for the device.**

Dr. James Hart 12/20/13 Dep. Tr., 800:3-8; Exhibit E) (emphasis added).

Moreover, the deposition testimony of Sean O'Bryan of regulatory affairs, confirmed that Ethicon could not withhold warnings based on an assumption that surgeons would otherwise know the risks:

> Q: When you worked on that project, it was your understanding from an FDA regulatory perspective it would not be legitimate to not include warnings of potentially significant adverse events based on a decision that the surgeons would figure that out on their own?
>
> A: No, that's correct.

(Sean O'Bryan 5/18/12 Dep. Tr. at 107:14-21, attached as Exhibit F). This testimony completely invalidates any opinion that would allow Ethicon to fail to warn based on an unverifiable claim or assumption that physicians would know the risks without being warned. Of course, that is not a standard; rather, it is an excuse created to explain the failure to provide warnings in accordance with the applicable standards.

B. Dr. Elser's is admittedly not an expert with regard to design, and her opinion that mesh is biocompatible should be precluded.

Dr. Elser is admittedly not an expert in design, and her only design opinion claims that the literature shows that the mesh is biocompatible. (Defense Brief at 8). Dr. Elser's literature review does not qualify her to offer opinions regarding the design of the mesh as it relates to biocompatibility, particularly where she has admitted a lack of expertise in that area, and where she has ignored data that is contrary to her opinion. Dr. Elser has already indicated a lack of expertise in the area of mesh design and materials:

Q. You don't consult as a materials expert, correct?

A. No.

Q. And you have never designed a mesh, correct?

A. No.

Q. And you haven't studied any explants of mesh, correct?

A. No.

(Dr. Elser 11/5/15 Dep. Tr. at 128:23-129:8, attached as Exhibit G).

In addition to her admitted lack of expertise, Dr. Elser cherry-picks information and testing for her biocompatibility opinions, as she did in her warning opinions, ignoring contrary testing and data. She disregards Ethicon's own internal testing in regards to the biocompatibility of certain meshes:

Q. The Internal Ethicon studies or documents related to laser-cut mesh being stiffer than mechanically cut mesh, you have those documents no weight or bearing in forming your opinions and conclusions in this case regarding the TVT-O and TVT?

A. Right. What happens in the lab in an artificial setting is not important to me compared to how the sling reacts clinically and how it performs.

> Q. My question was: Did you give the internal Ethicon studies or documents related to the laser-cut mesh being stiffer or not stiffer than the mechanically cut mesh any weight or bearing in forming your opinions in this caser regarding the TVT or TVT-O device?
>
> A. No.

(Dr. Elser 3/30/16 Dep. Tr. at 40:16-41:3, 41:7-41:13, Exhibit B).

This Court has previously recognized the importance of an expert's admission that he is not an expert. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Elser, who admitted on multiple occasions during her recent deposition that she is not an expert on design. In addition, she has selectively cherry-picked data, making her methodology for reaching her opinions unreliable. *Barber v. United Airlines Inc.*, 17 Fed. Appx. 433, 437 (7th Cir. 2001) (holding that a "selective use of the facts fails to satisfy the scientific method and *Daubert*). As such, she should be precluded from giving any opinions related to design of the subject products, including offering opinions that the mesh is biocompatible.

C. Dr. Elser's opinions about her personal re-operation rate should be excluded, as it is based on unreliable and untestable data and methodology.

Plaintiffs do not seek to preclude Dr. Elser from testifying generally about safety and efficacy rates of the TVT and TVT-O, as reported in the literature. However, Plaintiffs object to Dr. Elser's opinion regarding a specific revision rate of 4.5% with slings in her clinical practice. She cannot provide a numerator, a denominator, a time period, the number of patients involved, or any other methodology or statistical analysis that would give the opinion reliability, and would allow Plaintiffs to test the veracity of the opinion. (*See* Plaintiff's Memorandum at 12-14). Defendants rely heavily upon this Court's prior decision in *Bellew*, allowing Dr. Robboy to correlate tissue reactions he observed in his own practice with scientific literature and conclude

that the plaintiff had a mild tissue reaction. (Defendant's brief at 11-12, citing No. 2:13-CV-22473 [Docket 265] at 39-40. (S.D. W. Va. Nov. 20, 2014)).

The situation with Dr. Robboy in *Bellew* is readily distinguishable. Dr. Robboy was offering a general, qualitative analysis of observed tissue reactions observed in his clinical practice. In contrast, Dr. Elser is offering a specific, quantitative analysis of sling revision rates observed in her clinical practice, without providing the data or methodology she used to arrive at this 4.5% number. In addition, Dr. Elser admits that this re-operation rate includes slings made from other polypropylene material not at issue in these cases, adding to the risk of confusing and misleading the jury. (*See* Plaintiff's Memorandum at 12-14). This court should preclude Dr. Elser from offering an opinion regarding any specific, numerical percentage for revision rates seen in her clinical practice.

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Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERCE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Thomas P. Cartmell
Attorney for Plaintiffs